IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application: Manegold et al.	)	Group Art Unit: 1612
Serial No. 10/783,080	)	Examiner: Snigdha Maewall
Filed: February 20, 2004	)	Atty. Docket No. 3071.TDM

For: DISSOLVABLE FILM AND METHOD OF MANUFACTURE

BRIEF ON APPEAL

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

Applicants hereby appeal the decision of the Primary Examiner finally rejecting claims 1-20.

A copy of the claims involved in this appeal is set forth in the *Claims appendix*.

(i) *Real party in interest*

The real party in interest is Henkel Corporation, successor in interest to National Starch and Chemical Investment Holding Corporation.

(ii) *Related appeals and interferences*

There are no appeals or interferences known to applicants which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(iii) *Status of Claims*

Claims 1-20 are pending.

Claims 1-9 and 14-20 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Majeti (U.S. Patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1).

Claims 1-20 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Ballard (U.S. Publication No. 2005/0013847) in view of Kulkarni et al. (WO 2004/096174 A1).

The rejection of claims 1-20 is being appealed.

(iv) *Status of Amendments*

No amendment following final rejection was made. Arguments overcoming the outstanding Section 112 rejection have been considered and are to be entered upon the filing of this brief.

(v) *Summary of claimed subject matter*

Independent claim 1 is directed to an active-containing dissolvable film prepared by solubilizing or dispersing an active ingredient in an aqueous environment, forming a mixture comprising the active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture. Page 2, lines 4-8. The active ingredient has a water solubility of less than about 1 g/4mL at room temperature and is present in the film in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable

film. Page 2, lines 9-14

Independent claim 12 is directed to a method of making an active-containing dissolvable film comprising an active ingredient. The method comprises solubilizing or dispersing an active ingredient in an aqueous environment, forming a mixture of the dispersed or solubilized active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture. Page 2, line21 to page 3, line 1. The active ingredient used in the method of the invention has a water solubility of less than about 1g/4mL at room temperature and used in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film. Page 3, lines 2-7.

Independent claim 14 is directed to a dissolvable caffeine-containing film comprising at least about 18 % by dry weight of caffeine based on the weight of said film. Page 2, lines16-18.

(vi) *Grounds of rejection to be reviewed on appeal*

A. WHETHER THE SUBJECT MATTER OF CLAIMS 1-9, 14 AND 15 IS UNPATENTABLY OBVIOUS OVER MAJETI (U.S. PATENT NO. 5,599,554) IN VIEW OF KULKARNI ET AL. (WO 2004/096174 A1).

(a1) WHETHER THE SUBJECT MATTER OF CLAIMS 14 AND 15 IS OBVIOUS OVER MAJETI (U.S. PATENT NO. 5,599,554) IN VIEW OF KULKARNI ET AL. (WO 2004/096174 A1).

B. WHETHER THE SUBJECT MATTER OF CLAIMS 1-20 IS UNPATENTABLY OBVIOUS OVER BALLARD (U.S. PUBLICATION NO. 2005/0013847) IN VIEW OF KULKARNI ET AL. (WO 2004/096174 A1).

(b1) WHETHER THE SUBJECT MATTER OF CLAIMS 10 AND 11 IS OBVIOUS OVER BALLARD (U.S. PUBLICATION NO. 2005/0013847) IN VIEW OF KULKARNI ET AL. (WO 2004/096174 A1).

(b2) WHETHER THE SUBJECT MATTER OF CLAIMS 14 AND 15 IS OBVIOUS OVER BALLARD (U.S. PUBLICATION NO. 2005/0013847) IN VIEW OF KULKARNI ET AL. (WO 2004/096174 A1).

(b3) WHETHER THE SUBJECT MATTER OF CLAIMS 18 AND 19 IS OBVIOUS OVER BALLARD (U.S. PUBLICATION NO. 2005/0013847) IN VIEW OF KULKARNI ET AL. (WO 2004/096174 A1).

(vii) *Argument*

A. Claims 1-9, 14 and 15 are patentable over Majeti in view of Kulkarni et al.

Claims 1-9, 14 and 15 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Majeti (U.S. Patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1).

Claims 1-9 and 14-20 under 35 U.S.C. § 103(a) as being unpatentable over Majeti (U.S. Patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1). Applicants disagree.

Applicants have discovered that actives having low solubility levels, i.e., actives having solubility levels of less than about 1g/4mL at room temperature can be incorporated into a dissolvable film and delivered in an amount effective to impart a desired action.

Majeti discloses a transdermal or transmucosal administered composition containing nicotine or a combination of nicotine and caffeine. Pharmaceutically acceptable carriers include transdermal and buccal patches and bioadhesive and mucoadhesive films or other formulations suitable for administration (co. 3, lines 37-43). At Col. 4, lines 31-40, discloses:

> The transdermal or transmucosal carriers of the present invention may comprise a single layer or multi-layer system. Typically these carriers comprise an adhesive layer, which in a single layer system, releases the nicotine and caffeine or caffeine equivalent. The adhesive layer may be mucoadhesive, bioadhesive, pressure sensitive or require moisture for adhesion. Multi-layer systems generally will also comprise at least one reservoir layer, a backing component, and may include other layers of varying solubility which aid in controlling the release rate of actives being administered.

Thus, whether a single layer or a multilayer system, one layer is an adhesive layer, believed to the "bioadhesive and mucoadhesive films" referred to at col. 3, lines 41. There is no disclosure of a dissolvable film in Majeti, or that any active, let alone actives that are not very soluble like caffeine, may be administered using a dissolvable film as disclosed and claimed by applicants.

While Kulkarni discloses dissolvable films, it is silent as to whether actives having low levels of solubility can be incorporated into a dissolvable film at levels where they exert a desired effect when administered. There is nothing in the combined disclosure that would suggest that actives having a low level of solubility, such as caffeine, could be delivered using the dissolvable film of Kulkarni. The combined disclosures would not have suggested to one of ordinary skill in the art that the caffeine of Majeti could be administered using the film of Kulkarni.

The invention of claims 1-9, 14 and 15 would not have been obvious to one skilled in the art from the combined disclosures of Majeti and Kulkarni.

Reversal of the examiner's Section 103 rejection of claims 1-9, 14 and 15 as being obvious over Majeti and Kulkarni is requested.

a1. Claims 14 and 15 are patentable over Majeti in view of Kulkarni et al.

Claim 14 is directed to a dissolvable caffeine-containing film comprising at least about 18 % by dry weight of caffeine based on the weight of said film. The dissolvable caffeine-containing film of claim 15 comprises from about 20 mg to about 30 mg of caffeine per single dosage film.

Caffeine has a low level of solubility, there is nothing in the combined disclosures of Majeti and Kulkarni to suggest that caffeine, in the amounts required in claims 14 and 15, could be administered using a dissolvable film, as claimed by applicants. The combined disclosures would not have suggested to one of ordinary skill in the art that the caffeine of Majeti could be administered using the film of Kulkarni.

The invention of claims 14 and 15 would not have been obvious to one skilled in the art from the combined disclosures of Majeti and Kulkarni.

Reversal of the examiner's Section 103 rejection of claims 14 and 15 as being obvious over Majeti and Kulkarni is requested.

B. Claims 1-20 are patentable over Ballard in view of Kulkarni et al.

Claims 1-20 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Ballard (U.S. Publication No. 2005/0013847) in view of Kulkarni et al. (WO 2004/096174 A1).

Ballard discloses gel films formed of structured alginate used to deliver actives for oral care to the oral cavity. Ballard does not teach or even suggest that the active can be solubilized or dispersed in an aqueous environment and mixed with film forming agents to form a dissolvable film. Kulkarni adds nothing to the disclosure of Ballard to render the claimed

invention obvious. While Ballard and Kulkarni discloses films useful in administering actives, there is no disclose or suggestion that actives having low levels of solubility can be incorporated into a dissolvable film at levels where a desired effect is obtained following administration. There is no disclosure that would suggest that actives, such as caffeine, could be successfully delivered using the film of Ballard or Kulkarni so as the render the claimed invention obvious.

The invention of claims 1-20 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkarni.

Reversal of the examiner's Section 103 rejection of claims 1-20 as being obvious over Ballard and in view of Kulkarni is requested.

b1. Claims 10 and 11 are patentable over Ballard in view of Kulkarni et al.

Claim 10 is directed to an active-containing film comprising the active and film forming ingredients, which film forming ingredients comprise a starch component, at least 85% of which is a modified starch. Claim 11 limits the modified starch to a hydroxyalkylated starch, a succinated starch, or mixture thereof.

Caffeine has a low level of solubility, there is nothing in the combined disclosures of Ballard and Kulkarni to suggest that caffeine, which has a low solubility level, could be administered in amounts effective to impart a desired action using a dissolvable film that comprises starch.

The invention of claims 10 and 11 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkarni.

Reversal of the examiner's Section 103 rejection of claims 10 and 11 as being obvious over Ballard and in view of Kulkarni is requested.

b2. Claims 14 and 15 are patentable over Ballard in view of Kulkarni et al.

Claim 14 is directed to a dissolvable caffeine-containing film comprising at least about 18 % by dry weight of caffeine based on the weight of said film. The dissolvable caffeine-containing film of claim 15 comprises from about 20 mg to about 30 mg of caffeine per single dosage film.

Caffeine has a low level of solubility, there is nothing in the combined disclosures of Ballard and Kulkarni to suggest that caffeine, in the amounts required in claims 14 and 15, could be administered using a dissolvable film, as claimed by applicants.

The invention of claims 14 and 15 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkarni.

Reversal of the examiner's Section 103 rejection of claims 14 and 15 as being obvious over Ballard and in view of Kulkarni is requested.

b3. Claims 18 and 19 are patentable over Ballard in view of Kulkarni et al.

Claim 18 is directed to a method of administering an active ingredient to an individual by applying a dissolvable film to a moist area of an individual, specifically to traumatized tissue. Claim 19 requires that the traumatized tissue be skin tissue.

There is no disclosure of administering actives to by application of a film to traumatized tissue in either of Ballard or Kulkarni; as such their combination also fails to suggest the claimed

subject matter.

The invention of claims 18 and 19 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkarni.

Reversal of the examiner's Section 103 rejection of claims 18 and 19 as being obvious over Ballard and in view of Kulkarni is requested.

Respectfully submitted,

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(viii) *Claims appendix*

1. An active-containing dissolvable film prepared by solubilizing or dispersing an active ingredient in an aqueous environment, forming a mixture comprising the active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture, said active ingredient having a water solubility of less than about 1 g/4mL at room temperature and being present in the film in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film.

2. The film of claim 1 wherein the active ingredient has a water solubility of less than about 1 g/10mL at room temperature.

3. The film of claim 1 wherein the mixture is in the form of a solution.

4. The film of claim 3 wherein a solution is formed upon the application of heat and/or agitation of the mixture.

5. The film of claim 1 wherein the mixture is in the form a suspension.

6. The film of claim 3 wherein said active ingredient is caffeine.

7. The film of claim 6 comprising at least about 18 % by dry weight of caffeine based on the weight of the final formulated film.

8. The film of claim 7 comprising at least about 20 % by dry weight of caffeine.

9. The film of claim 8 comprising at least about 25 % by dry weight of caffeine.

10. The film of claim 1 wherein said film-forming ingredients comprise a starch component comprising at least about 85 % modified starch.

11. The film of claim 10 wherein the starch is selected from the group consisting of a hydroxyalkylated starch and a succinated starch.

12. A method of making an active-containing dissolvable film comprising an active ingredient, the method comprising solubilizing or dispersing an active ingredient in an aqueous environment, forming a mixture of the dispersed or solubilized active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture, said active ingredient having a water solubility of less than about 1g/4mL at room temperature and used in amounts

sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film.

13. The method of claim 12 wherein the mixture is in the form of a solution or in the form of a suspension.

14. A dissolvable caffeine-containing film comprising at least about 18 % by dry weight of caffeine based on the weight of said film.

15. A single dosage dissolvable film of claim 14 comprising from about 20 mg to about 30 mg of caffeine per single dosage film.

16. A method of administering an active ingredient to an individual needing or desiring said active ingredient, said method comprising applying the active-containing dissolvable film of claim 1 to a moist area of an individual, upon which application the active is released.

17. The method of claim 16, wherein the film is applied to the tongue.

18. The method of claim 16, wherein the film is applied to traumatized tissue.

19. The method of claim 18 wherein the traumatized tissue is skin.

20. The method of claim 17 wherein the active ingredient is caffeine.

(ix) *Evidence appendix*

NONE

(x) *Related proceedings appendix*

None